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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/914,872 | 02/07/2002 | John C. Alexander | 3179/1Z | 4170 |

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PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
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ST. LOUIS, MO 63006

EXAMINER

HUI, SAN MING R

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,872

Applicant(s)

ALEXANDER ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments filed December 6, 2005 have been entered. Claims 45-60 are added. Claims 1-44 are cancelled.

Claims 45-60 are pending.

After the amendments, the claims are directed to composition and method of treating cardiovascular disease comprising eplerenone, ramipril, and a loop diuretic. Since the claims are no longer directed to the elected specie, quinapril, the outstanding rejection is withdrawn. The examination will now be directed to ramipril.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO96/40257 ('257) from IDS filed September 5, 2001, Fossa (US patent 5,663,188), and Dahlstrom et al. (Am J Cardiol. 1993 Jan 21;71(3):29A-33A).

'257 teaches eplerenone as useful in treating congestive heart failure. '257 also teaches that a combination of other compounds that is a same class as eplerenone, diuretics and ACE inhibitors captopril as useful in treating heart failure (See page 9, lines 21-24, also page 6, lines 25 – page 7, line 6).

Fossa teaches ramipril as effective in treating congestive heart failure (See col. 1, lines 50-53; claims 15, 18, and 22 for example).

Dahlstrom et al. teaches furosemide, and/or spironolactone, and/or digoxin combined with ACE inhibitor captopril as effective in treating congestive heart failure (See the abstract and page 32A-33A, discussion Section).

The references do not expressly teach the combination of eplerenone, furosamide, and ramipril, in the herein claimed dosage, in a single composition. The references do not expressly teach the use of such combination in the method of treating congestive heart failure (CHF).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine eplerenone, furosamide, and ramipril, in the herein claimed dosage, into a single composition. It would have been obvious to one of ordinary skill in the art at the time of invention to employ the combination in a method of treating CHF.

One of ordinary skill in the art would have been motivated to combine eplerenone, furosamide, and ramipril, in the herein claimed dosage, into a single composition. The herein claimed agents are known to be useful in treating congestive heart failure, both individually or in combination, therefore, combining these agents into a single composition useful for the very same purpose, i.e., treating congestive heart failure, would be prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069). Furthermore, the optimization of result effect parameters (e.g., dosage range, dosing regimens) is obvious as being within the skill of the artisan. In addition, one of ordinary

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skill in the art would have been motivated to employ the combination in a method of treating CHF. Employing the combination of the herein claimed agents, which are known to be useful for treating CHF, would be reasonably expected to be effective, at least additive effect would be expected.

Response to Arguments

Applicant's arguments with respect to claims 45-60 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-

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0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


San-ming Hui
Primary Examiner
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